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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/091,602	04/19/1999	JOACHIM BUNGER	BEIERSDORF50	5123

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EXAMINER

TRAVERS, RUSSELL S

ART UNIT

PAPER NUMBER

1617

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/091,602

Applicant(s)
Benger et al

Examiner
R.S. Travers J.D., Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 31, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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The request for reconsideration filed March 31, 2003 has been received and entered into the file.

Applicant's arguments filed March 31, 2003 have been fully considered but they are not deemed to be persuasive.

Claims 2-10 are presented for examination.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 2-10 are rejected under 35 U.S.C. § 103 as being unpatentable over Matsumura et al, Shoji et al, and Ikekawa et al, in view of Ziolkowsky.

Matsumura et al, Shoji et al, and Ikekawa et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. This medicament is taught as useful for treating various etiological

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agents, to include those recited herein. Claims 3, 9 and 10 and the primary references, differ as to:

- 1) the employment of these medicaments dermally or cosmetically, and
- 2) administration levels of the medicaments.
- 3) recitation of decay prevention.

Ziolkowsky teaches the claimed compounds as useful for a dermal, cosmetic use. Possessing this teaching, the skilled artisan would have been motivated to employ the claimed compounds for the dermal, or cosmetic use herein claimed and enjoy a reasonable expectations of therapeutic success.

Determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed therapeutic methods.

Claim 9 specifically requires dermal pharmaceutical composition or cosmetic composition. Ziolkowsky employed the claimed compound in an dermal and cosmetic form, not specifically reciting another formulation. The skilled artisan would have seen

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dermal pharmaceutical composition or cosmetic compositions, and the administration of these compounds by these conventional means as residing in the skilled artisan purview.

The skilled artisan would have been motivated by the cited prior art antibacterial, or anti-fungal recitation to employ the claimed compounds for preventing, or retarding, microbial degradation. Possessing the Examiner cited prior art, the skilled artisan would have been motivated to employ the prior art antimicrobial compounds to retard decay, and enjoyed a reasonable expectation of success, absent information to the contrary

RESPONSE TO ARGUMENTS

Rebuttal arguments regarding the rejection under 35 USC 103 are not convincing. Examiner cited prior art teachings the instant active agents as broadly biocidal, to include those etiological agents herein claimed. These biocidal agents would have been seen by the skilled artisan to be useful for any biocidal use to include dermal, hair, or nails as herein claimed, absent contraindications.

Compounds taught as biocidal and efficacious intra peritoneally would have been seen as useful, and safe, for dermal application desiring the identical biocidal therapeutic outcome. The skilled artisan would be apprized of all conventional

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medicament application methods and possessing the biocidal teachings in the Examiner cited prior art would be motivated to employ compounds old and well known as biocides for this use generally. Examiner notes the instant claims are not directed to one, or another, biocidal mode of action, rendering rebuttal arguments regarding such modes of action moot.

That the instant compounds exhibit toxicity would not contraindicate dermal use. In the instant case, this would not contraindicate in view of the prior art use intra peritoneally. Applicants have additionally misconstrued Examiner burden with regard to obviation. Predictability is not the criteria for obviation; with the reasonable expectation of therapeutic success being the Examiner's burden: with that burden met in the instant case.

Applicants' rebuttal arguments based on Matsumura et al are unconvincing. Matsumura et al teach the use of the claimed compounds for controlling both gram positive and gram negative microbes, that one or another microbe possessed a higher MIC fails to teach away from employing these compounds on bacterial generally. Examiner notes the claims are not limited to gram negative bacteria, rendering the rebuttal arguments moot.

Attention is directed to Ziolkowsky, teaching the claimed compounds as useful for treating hair, thereby rendering obvious the instant use of these compounds for treating hair, or scalp. A teaching of hair treatment with the claimed active ingredients

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teaches employing the claimed methods for the use herein intended. Absent contraindications, the skilled artisan possessing the Ziolkowsky teaching, would employ the recited compounds as herein claimed and enjoy a reasonable expectation of therapeutic success.

Decay, as normally envisioned by those of normal skill in the art, would have been seen as resultant from microbial action. To employ old and well known biocidal agents to retard decay would have been motivated by the broad biocidal use set forth in the Examiner cited prior art. Possessing this teaching the skilled artisan would have seen employing biocidal active ingredients to retard decay as obvious.

As stated above, determining the active ingredient dosage level required to effect optimal therapeutic benefit is well within the Skilled Artisan's purview and the benefits of achieving such maximization obvious, to said skilled artisan. The claims merely recite the obvious employment of old and well known active ingredients, carriers and excipients. Thus, the only issue presented in the instant application is the obviousness of the claimed therapeutic methods.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a). The practice of automatically extending the

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shortened statutory period an additional month upon the filing of a timely first response to a final rejection has been discontinued by the Office. See 1021 TMOG 35.

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

Any inquiry concerning this communication should be directed to Russell Travers at telephone number (703) 308-4603.



Russell Travers J.D., Ph.D.
Primary Examiner
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